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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/617,038

07/11/2003

Peter Andersen

SSISAUSA

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270 7590 05/19/2008

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

05/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/617,038	Applicant(s) ANDERSEN ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28April2008, 11January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-10,12,13,16,17 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-10,12,13,16,17 and 24-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. **THE FINALITY OF THE LAST OFFICE ACTION IS HEREBY VACATED.**
2. Applicants' Response to Office Action, received 11 January 2008, is acknowledged.
Claims 6-24 have been amended. Claim 23 has been canceled.
3. Applicants' Notice of Appeal, received 28 April 2008, is acknowledged.
4. Claims 6-10, 12, 13, 16, 17, and 24-27 are pending and under consideration.

Rejections Withdraw/Moot

5. The rejection of claims 6-8, 24, and 25 under 35 U.S.C. 112, second paragraph, indefiniteness, is withdrawn in light of the claim amendments.
6. The rejection of claim 23 under 35 U.S.C. 112, second paragraph, indefiniteness, is moot in light of the cancellation of the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 12, and 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Horwitz (U.S. Pat. No. 5,108,745).

One embodiment of claim 1 is a therapeutic vaccine against tuberculosis comprising ≥ 1 polypeptide or fragments thereof and a pharmaceutically acceptable adjuvant, which polypeptides are upregulated or expressed during the latent state of the mycobacteria infection.

Claim 12 is vaccine comprising antigen components with therapeutic activity against tuberculosis comprising ≥ 1 polypeptide or fragment thereof, which polypeptides are

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upregulated or expressed during the latent stage of the mycobacteria infection, combined with antigen components with prophylactic activity.

Claim 13 is the vaccine of claim 12 wherein the antigen component with prophylactic activity is CFP10.

Horwitz teaches a therapeutic vaccine against *M. tuberculosis* comprising ≥ 1 extracellular product of *M. tuberculosis* and a pharmaceutically acceptable adjuvant (claims 13-17; col. 4, lines 23-26). In the absence of evidence to the contrary, the extracellular products of *M. tuberculosis* contain the required ≥ 1 polypeptide or fragments thereof (such as CFP10) which are upregulated or expressed during the latent state of the mycobacteria infection.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 6-10, 12, 13, 16, 17, and 24-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a therapeutic vaccine comprising: 1) either a fragment of a polypeptide which is upregulated or expressed during the latent stage of a tuberculosis infection, or, 2) an amino acid sequence which has $\geq 70\%$ identity to SEQ ID NOs:1-45 or a fragment of SEQ ID NOs:1-45.

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The specification provides vaccine examples of only whole BCG, ESAT6, Rv2031c, and Rv0569, and two fragments of Rv2031c. The specification does not teach any vaccines comprising $\geq 70\%$ identity to SEQ ID NOs:1-45 or a fragment of SEQ ID NOs:1-45 except for to peptide epitopes, i.e., peptide 2 and 9 which are subsequences of SEQ ID NO:24.

Therefore the claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, i.e., vaccines comprising fragments of SEQ ID NOs:1-23, 25-45, or vaccines comprising sequences $\geq 70\%$ identity to SEQ ID NOs:1-45.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

May 1, 2008